REMARKS

Claims 1, 3, 6, 8, 11 and 13-18 are pending in this application. By this Amendment, claims 1, 6 and 17 are amended, and new claim 18 is added. Support for the amendments and the new claim can be found, for example, in the specification (see paragraphs [0021], [0023], [0024], [0026], [0032], [0034], [0036], [0037] and [0039]). No new matter is added.

In view of the foregoing amendments and the following remarks, reconsideration and allowance of the claims are respectfully requested.

Entry of the amendments is proper under 37 CFR §1.116 because the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (as the amendments amplify issues previously discussed throughout prosecution); and (c) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

I. Objection to the Claims

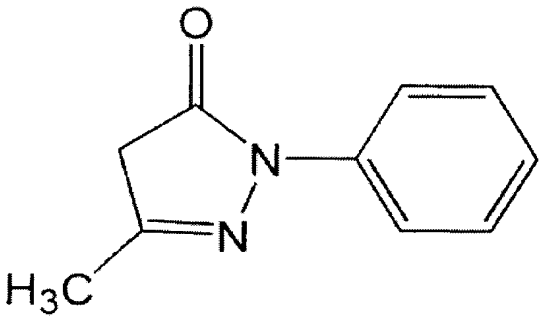
The Patent Office objects to claim 17 due to informalities. Claim 17 is amended to obviate the objection. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

II. Rejections Under 35 U.S.C. §103

The Patent Office (1) rejects claims 1, 3, 6, 8, 11, 13 and 14 under 35 U.S.C. §103(a) as allegedly being unpatentable over JP 10-279480 to Uchiumi et al. ("Uchiumi") in view of JP 10-265373 to Koide et al. ("Koide"); and (2) rejects claims 1, 3, 6, 8 and 15-17 under 35 U.S.C. §103(a) as allegedly being unpatentable over Uchiumi in view of U.S. Patent No. 6,248,350 to Mori et al. ("Mori '350"). These rejections are respectfully traversed.

Uchiumi discloses a drug formulation comprising a divided dose of 3-methyl-1-phenyl-2-pyrazolin-5-one ("EDV") including: (1) 1-100 mg for oral administration; (2) 0.01-50 mg for intravenous injection; and (3) 1-100 mg for intrarectal administration (Uchiumi, Abstract). The Patent Office acknowledges the Uchiumi fails to disclose concentrations of the carrier formulation and the inclusion of specific excipients recited in claims 1 and 6. The Patent Office applies Koide and Mori '350 to allegedly remedy these deficiencies of Uchiumi. However, for at least the reasons presented below, Uchiumi, Koide and Mori '350, in any combination, would not have rendered obvious the subject matter of claims 1 and 6.

Claim 1 recites:

> A percutaneous absorption preparation containing 3-methyl-1-phenyl-2-pyrazolin-5-one, comprising, as an active
>
> 
>
>
> ingredient, 0.1 to 30 percent by mass of 3-methyl-1-phenyl-2-pyrazolin-5-one represented by the following formula:
>
> or a medically acceptable salt thereof in an aqueous base;
>
> a percutaneous absorption accelerator selected from the group consisting of oleyl alcohol, lauryl alcohol, cetyl alcohol, crotamiton, and cyclodextrin;
>
> a reaction speed adjuster selected from the group consisting of citric acid, lactic acid, and tartaric acid; and
>
> a dissolving agent selected from the group consisting of N-methyl-2-pyrrolidone, macrogol, isopropanol, metha oil, butylenes glycol, oleyl alcohol, and isopropyl myristate,
>
> wherein the aqueous base comprises:
>
> a water-soluble polymer selected from the group consisting of sodium polyacrylate, starch acrylate, and methyl acrylate/acrylic acid 2-ethylhexyl copolymer resin emulsion;

a cross-linking agent selected from the group consisting of aluminum hydroxide, and magnesium aluminum hydroxide; and

a polyhydric alcohol selected from the group consisting of ethylene glycol, propylene glycol, trimethylene glycol, and glycerin; and

water.

Claim 6 recites similar features.

Claims 1 and 6 should be read in conjunction with the Declaration Under 37 C.F.R. §1.132 ("Declaration") of Jun Mori, submitted with the Amendment on March 3, 2010. A copy of the Declaration is attached herewith. The Declaration was submitted in response to the September 4, 2009 Office Action, which rejected claims 1 and 6 under 35 U.S.C. §103(a) over Uchiumi in view of Koide and EP 1 174 132 to Mori et al. ("Mori '132"). The Patent Office applies Mori '350 in the present rejection as allegedly addressing features similar or identical to Mori '132.

The Declaration offers the results of experimental tests directed to comparative compositions of Mori '132 and Koide. With respect to Koide, comparative tests directed to Example 3 of Koide are included in the Declaration, selected as the composition demonstrating the highest adhesion of that reference. With respect to Mori '132, comparative tests directed to Examples 3 and 4 are included in the Declaration, as compositions closest to the percutaneous absorption preparation recited in claims 1 and 6.

The Declaration describes experimental tests that were performed to measure and observe the formability, adhesiveness, and skin transmission properties of: (1) Preparation A, a percutaneous absorption preparation according to Example 1 of the present specification; (2) Preparations B and C, two adhesive preparations according to Example 3 of Koide, where C is similar to B except that 52.75 parts of pure H_2O were used in place of 3 parts EDV and 49.75 parts pure H_2O; (3) Preparations D and E, two absorption preparations according to

Example 3 of Mori '132, where E is similar to D except that no EDV was added; and (4) Preparations F and G, two absorption preparations according to Example 4 of Mori '132, where G is similar to F except that no EDV was added (see specification, paragraphs [0038] and [0039]; Koide, Table 1; and Mori '132, paragraphs [0050] and [0051]). Skin transmission property tests identical to those disclosed in the specification were conducted on each of Preparations A-G (specification, paragraph [0042]).

With reference to Table 1 of the Declaration, the results clearly show that the percutaneous absorption preparations recited in claims 1 and 6 have unexpectedly superior formability, adhesiveness and skin transmission properties relative to the comparative preparations of Koide and Mori '132. More specifically: (1) the skin transmission property of Preparations B and C **decreased by approximately 31.4%**; (2) the skin transmission property of Preparations D and E **decreased by approximately 67.6%**; and (3) the skin transmission property of Preparations D and E **decreased by approximately 21.5%** when compared to Preparation A, as recited in claims 1 and 6. None of the applied references provide any reason or rationale for one of ordinary skill in the art to have expected that the percutaneous absorption preparation recited in claims 1 and 6 would have yielded the vastly improved results shown in the Declaration. Mori '350, as presently applied, does not overcome the deficiencies of Uchiumi, Koide and Mori '132.

Based on the above, Applicants respectfully submit that the percutaneous absorption preparation of claims 1 and 6 would not have been rendered obvious by Koide, Mori '350 and Uchiumi, at least because the evidence presented herewith establishes that the preparation of claims 1 and 6 possess improved and unexpected properties relative to the alleged disclosures of the Mori '132 and Koide. The remaining claims variously depend from claims 1 and 6 and, likewise, would not have been rendered obvious by the applied references for at least the

reasons set forth above with respect to claims 1 and 6, as well as for the additional features recited therein.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

III. New Claim

By this Amendment, new claim 18 is added. New claim 18 depends from claim 1, and, thus, is patentable for at least the reasons discussed above with respect to claim 1, as well as for the additional feature it recites. Specifically, new claim 18 is directed to the components of Preparation A in the Declaration.

Prompt examination and allowance of new claim 18 is respectfully requested.

IV. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

James A. Oliff
Registration No. 27,075

Sarah Lhymn
Registration No. 65,041

JAO:SQL/rle

Attachment:
Copy of Declaration Under 37 C.F.R. §1.132 Previously Submitted on March 3, 2010

Date: September 8, 2010

OLIFF & BERRIDGE, PLC
P.O. Box 320850
Alexandria, Virginia 22320-4850
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry of this filing; Charge any fee due to our Deposit Account No. 15-0461